Subject

(d) Air Transport Association (ATA) of America Code 27: Flight controls.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

A broken aileron servo actuator centering spring rod was discovered on a model G100 aircraft during a routine scheduled maintenance inspection. * * * This latent failure of a centering spring rod, if not detected and corrected, in conjunction with the disconnection of the normal mechanical control system of the same servo actuator would lead to loss [of] control of the flight control surface [aileron or elevator]. This condition would reduce the control capability of the airplane and imposes a higher workload on the flight crew reducing their ability to cope with adverse operating conditions.

Compliance

(f) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Inspection

(g) Within 12 months after the effective date of this AD, do the actions specified by paragraph (g)(1) or (g)(2) of this AD, as applicable.

(1) For Model Gulfstream G150 airplanes: Do a one-time detailed inspection of the aileron control servo actuators to detect fractured or broken centering spring rods, in accordance with the Accomplishment Instructions of Gulfstream Service Bulletin 150–27–123, Revision 1, dated January 27, 2011.

(2) For Model Galaxy and Gulfstream 200 airplanes: Do a one-time detailed inspection of the aileron and elevator control servo actuators to detect fractured or broken centering spring rods, in accordance with the Accomplishment Instructions of Gulfstream Service Bulletin 200–27–374, Revision 1, dated January 27, 2011.

Corrective Actions

(h) If any centering spring rod is found fractured or broken during any inspection required by this AD: Before further flight, replace the centering spring rod in accordance with a method approved by the Manager, International Branch, ANM 116, Transport Airplane Directorate, FAA, or the Civil Aviation Authority of Israel (CAAI) (or its delegated agent).

Credit for Actions Accomplished in Accordance With Previous Service Information

(i) Actions done before the effective date of this AD in accordance with Gulfstream Service Bulletin 150–27–123 or 200–27–374, both dated October 27, 2010, are considered acceptable for the actions required by paragraph (g) of this AD.

FAA AD Differences

Note 1: This AD differs from the MCAI and/or service information as follows: The MCAI AD does not specify a corrective action for fractured or broken rods; however, paragraph (h) of this AD requires corrective action.

Other FAA AD Provisions

(j) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Mike Borfitz, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–2677; fax (425) 227–1149. Information may be e-mailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

Related Information

(k) Refer to MCAI Civil Aviation Authority of Israel Airworthiness Directives 27–10–11–03, dated December 6, 2010, and 27–10–12–29, dated January 4, 2011; and Gulfstream Service Bulletins 150–27–123 and 200–27–374, both Revision 1, both dated January 27, 2011; for related information.

Issued in Renton, Washington, on July 6, 2011.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–17697 Filed 7–13–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 203

[Docket No. FDA–2011–N–0446]

Removal of Certain Requirements Related to the Prescription Drug Marketing Act; Opportunity for Public Comment

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to remove a section of the Prescription Drug Marketing Act (PDMA) regulations requiring that prior to the completion of any wholesale distribution of a prescription drug, an unauthorized distributor must provide to the purchaser ''a statement identifying each prior sale, purchase, or trade of such drug,'' starting with the manufacturer, and that the identifying statement (also known as the ''pedigree'') must include certain information about the drug and each prior sale, purchase, or trade. This action is being taken in response to longstanding issues, including an injunction currently in effect, regarding the application of and compliance with this requirement. FDA is also announcing that it intends to exercise enforcement discretion with respect to certain requirements of the regulation while the rulemaking is pending and with respect to the statutory pedigree requirements of the PDMA, as long as the pedigree identifies the names and addresses of the last authorized distributor of record that handled the drug and the associated dates of transactions involving that last authorized distributor of record and the drug, as well as the names and addresses of all subsequent unauthorized distributors that handled the drug and the corresponding dates of those transactions.

DATES: Submit either electronic or written comments on the proposed rule by September 12, 2011.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2011–N–0446, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *FAX:* 301–827–6870.
- *Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Karen Rothschild, Center for Drug Evaluation and Research, Food Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–3689, *e-mail: karen.rothschild@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The PDMA (Pub. L. 100–293) was enacted on April 22, 1988, and was modified by the PDA (Pub. L. 102–353) on August 26, 1992. The PDMA, as modified, amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to establish restrictions and requirements relating to various aspects of human prescription drug marketing and distribution. The primary purpose of the PDMA was to increase safeguards to prevent the introduction and retail sale of substandard, ineffective, and counterfeit drugs into the U.S. drug supply chain. Among other things, the PDMA, in section 503(e)(1)(A) of the FD&C Act (21 U.S.C. 353), requires a wholesale distributor ''who is not the manufacturer or authorized distributor of record'' to provide drug pedigrees to purchasers ''identifying each prior sale, purchase or trade of such drug (including the date of the transaction and the names and addresses of all parties to the transaction).''

On August 1, 1988, the Agency issued a letter that provided guidance on the PDMA for industry pending the issuance of implementing regulations (the 1988 guidance letter) (see attachment E of FDA's 2001 Report to Congress (*http://www.fda.gov/downloads/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/PrescriptionDrugMarketingActof1987/UCM203186.pdf*)). Among other issues, the 1988 guidance letter discussed drug pedigrees. The 1988 guidance letter stated that the necessary identifying information regarding all sales in the chain of distribution may start with the manufacturer or authorized distributor of record. As explained in an FDA 2001 Prescription Drug Marketing Act Report to Congress (2001 Report to Congress) (see *http://www.fda.gov/downloads/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/PrescriptionDrugMarketingActof1987/UCM203186.pdf*), it was the Agency's understanding at the time that the authorized distributor of record would be the distributor to whom the manufacturer first sold the drugs, not just any authorized distributor who happened to purchase the drugs somewhere along the distribution chain.

In the **Federal Register** of March 14, 1994 (59 FR 11842), we issued a proposed rule related to certain provisions of the PDMA. With respect to prescription drug pedigrees, the proposed rule provided in relevant part that the identifying statement for sales by unauthorized distributors must include ''the business name and address of all parties to each prior transaction involving the drug, starting with the manufacturer.'' (59 FR 11865). A final rule was issued in the **Federal Register** of December 3, 1999 (64 FR 67720) (the December 1999 final rule), with an effective date of December 4, 2000. The final rule contained provisions on prescription drug reimportation; wholesale distribution of prescription drugs by unauthorized distributors; the resale of prescription drugs by hospitals, health care entities, and charitable institutions; and distribution of prescription drug samples. In the December 1999 final rule, FDA responded to a comment objecting to the pedigree requirement as proposed because it would require an unauthorized distributor to provide information about all prior sales, purchases, or trades of the drug, starting with the manufacturer, even in cases where the seller from whom the distributor received the drug was an authorized distributor of record and did not provide any pedigree for the drug. The comment recommended revising the proposed rule to require that the pedigree only go back to the last authorized distributor of record (64 FR 67720 at 67747). FDA declined to revise the rule, explaining that the statute requires that the pedigree identify ''each prior sale, purchase, or trade of the drug'' and ''[t]here is no indication in [the] PDMA that Congress intended that the statement include only those sales, purchases, or trades since the drug was last handled by an authorized distributor.'' (64 FR 67720 at 67747).

The December 1999 final rule thus codified § 203.50(a) (21 CFR 203.50(a)), which follows section 503(e)(1)(A) of the FD&C Act, requiring that, before the completion of any wholesale distribution by a wholesale distributor of a prescription drug for which the seller is not a manufacturer or an authorized distributor of record, the seller must provide to the purchaser a statement (also referred to as a pedigree) identifying each prior sale, purchase, or trade of the drug. According to § 203.50(a), the identifying statement must include: The proprietary and established name of the drug; dosage; container size; number of containers; the lot or control numbers of the drug being distributed; the business name and address of all parties to each prior transaction involving the drug, starting with the manufacturer; and the date of each previous transaction.

After publication of the December 1999 final rule, we received many comments on, and held several meetings to discuss, the implications of the final regulations regarding, among other things, the pedigree provisions at § 203.50(a) requiring unauthorized distributors to provide a pedigree showing all prior sales going back to the manufacturer. Industry representatives of unauthorized distributors represented that they could not obtain the required pedigree showing all prior sales of the drugs they purchase because a large portion of these drugs are purchased from authorized distributors who are not required to provide pedigrees and who are unwilling to voluntarily provide them.[1] Industry representatives also claimed that implementation of this requirement could prevent as many as 4,000 smaller, unauthorized distributors from distributing many drugs to their

[1] FDA, The Prescription Drug Marketing Act Report to Congress, 2001 (*http://www.fda.gov/downloads/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/PrescriptionDrugMarketingActof1987/UCM203186.pdf*).

customers, putting the unauthorized distributors out of business.[2]

In the 2001 Report to Congress, we noted that we would be able to address some, but not all of the concerns raised by unauthorized distributors. We stated that we believed that ''the concerns related to continuing to exempt authorized distributors from the pedigree requirement and the exact meaning of the phrase *'each prior sale'* can be addressed only through statutory remedies.'' [3]

As a result of these comments, other informal communications that FDA had with industry, industry associations, and Congress, and the Agency's consideration of a petition for stay of action received on May 3, 2000, FDA delayed the effective date of several provisions of the December 1999 final rule until October 1, 2001, and reopened the administrative record to receive additional comments (65 FR 25639, May 3, 2000). In the **Federal Register** of March 1, 2001 (66 FR 12850), we announced our decision to further delay until April 1, 2002, the applicability of § 203.50, among other provisions. Further delays of the effective dates followed until December 1, 2006, to give us additional time to consider whether regulatory changes were appropriate and, if so, to initiate such changes (67 FR 6645, February 13, 2002; 69 FR 4912, January 23, 2003; 69 FR 8105, February 23, 2004).

While § 203.50 was stayed, the industry followed the advice given in the 1988 guidance letter, which, as noted previously, stated that the pedigree should include ''all necessary identifying information regarding all sales in the chain of distribution of the product, starting with the manufacturer or the authorized distributor.''

In the **Federal Register** of June 14, 2006 (71 FR 34249), we announced that FDA did not intend to further delay the effective date of certain regulations related to the PDMA, including § 203.50, and that the regulation would go into effect on December 1, 2006.

On September 20, 2006, a group of unauthorized wholesalers of prescription drugs filed a lawsuit against FDA in the U.S. District Court for the Eastern District of New York, seeking, among other things, a declaratory judgment that § 203.50(a) erroneously interprets the statutory requirement for pedigrees (21 U.S.C. 353(e)(1)(A)), and violates the U.S. Constitution's guarantees of equal protection and due process. (*RxUSA Wholesale, Inc.* v. *Dept. of Health and Human Servs.,* 467 F. Supp.2d 285 (E.D.N.Y. 2006)). On November 22, 2006, the plaintiffs moved for a preliminary injunction against implementation of the regulation, which, as noted previously, was scheduled to become effective on December 1, 2006. On December 8, 2006, the district court issued a preliminary injunction enjoining FDA from implementing § 203.50(a) (467 F.Supp. 2d at 292). The court concluded that the statute, unlike § 203.50(a), does not ''specifically or expressly require[] unauthorized distributors to provide pedigree information *all the way back to the manufacturer.''* 467 F. Supp. 2d at 290 (emphasis in original). The court stated that ''[u]nauthorized distributors would be unable to comply with'' the December 1999 final rule requirement to ''provide complete pedigree information for all prior sales up to the manufacturer'' because unauthorized distributors purchase drugs from authorized distributors ''who do not provide pedigree information.'' (467 F. Supp. 2d at 291). The district court concluded that plaintiffs had shown a likelihood of success on the merits of their claim because, in the court's view, the pedigree regulation undermined the purpose of the statute and was therefore arbitrary and capricious. (467 F. Supp. 2d at 291). The court also found that issuance of the preliminary injunction would benefit the public interest by preserving ''the status quo and the current practice in the industry.'' (467 F. Supp. 2d at 292).

The Agency appealed the district court's preliminary injunction order, but the district court's order was affirmed on July 10, 2008, by the U.S. Court of Appeals for the Second Circuit. (See *RxUSA Wholesale, Inc.,* v. *Dept. of Health and Human Servs.,* 285 Fed. Appx. 809 (2d Cir. 2008)). The appellate court explained that the PDMA ''does not specifically state whether'' a pedigree must ''extend back to the manufacturer, or whether it must only extend to the last authorized distributor. The parties offer differing textual interpretations, but we agree with the district court that for purposes of preliminary injunction the statute's language does not unambiguously compel one interpretation over another.'' (285 Fed. Appx. at 811). Moreover, the second circuit concluded that the district court had not abused its discretion in determining that the plaintiffs had shown a likelihood of success on the merits because § 203.50(a) requires unauthorized distributors to ''provide pedigree information that is currently held only by authorized distributors'' and the regulation is ''inconsistent with the position taken by the agency in its original 1988 guidance letter, and it runs directly counter to the 20-year history of industry reliance on the FDA's initial position.'' (285 Fed. Appx. at 811).

The district court's preliminary injunction, as affirmed by the circuit court, halted FDA's implementation of the requirements of § 203.50(a). Specifically, the order enjoins FDA from implementing the requirement in § 203.50(a) that a pedigree identify each prior sale or trade of a drug back to the drug's original manufacturer and the requirement that specifies the types of information that must be included in the pedigree, including lot numbers and container sizes.

Under the district court's order, unauthorized distributors are only required to provide pedigrees that include information regarding transactions going back to either the manufacturer or the last authorized distributor of record that handled the drugs. In addition, as specified in the FD&C Act, all pedigrees must include the dates of the listed transactions and the names and addresses of all parties to those transactions. We recognized that these circumstances resulting from the court's order could lead to confusion and possible disruptions or delays in the nation's drug distribution system for wholesale distributors operating outside of the court's jurisdiction and could provide an undue advantage to certain wholesaler distributors. Therefore, we announced that we would exercise enforcement discretion in a manner consistent with the court's opinion throughout the rest of the country.

II. Proposed Regulation

FDA is now proposing to remove § 203.50(a). Over the past 20 years, we have endeavored to ensure that the pedigree requirements in our regulations are consistent with congressional intent and provide appropriate accountability to protect our nation's drug supply. We have made a good faith effort to implement the requirements in § 203.50(a) consistent with the language of the PDMA through public meetings, **Federal Register** documents requesting comments, meetings with the wholesale industry, Members of Congress, and others, a Report to Congress, and other actions. For the various reasons discussed earlier, § 203.50(a) has been effective for only a total of 7 days since the finalization of the rule in 1999. As explained previously, there have been serious ongoing concerns about the

[2] (See footnote 1 of this document.)

[3] (See footnote 1 of this document.)

effect that full implementation of the statutory pedigree requirements, as codified in § 203.50(a), would have on the nation's drug supply and on wholesaler distributors. Therefore, in light of the courts' opinions, we are proposing to remove § 203.50(a).

By proposing to remove § 203.50(a), we would remove the requirement in the regulation that the pedigree identify each prior sale or trade of a drug back to the drug's manufacturer. In addition, this proposal would remove the requirement in the regulation that the identifying statement include certain information, such as the proprietary and established name of the drug, the dosage, container size, number of containers, the drug's lot or control number(s), the business name and address of all parties for each prior transaction, starting with the manufacturer, and the date of each previous transaction. While the rulemaking to remove the regulation is pending, we intend to exercise enforcement discretion with respect to all of these requirements in § 203.50(a).

We note that even with the removal of § 203.50(a), the pedigree requirements of section 503(e)(1)(A) of the FD&C Act would still be in effect. However, with respect to these statutory pedigree requirements, the Agency intends to exercise enforcement discretion and not initiate an enforcement action against any wholesalers for failing to provide a pedigree that goes back to the manufacturer or for failing to include the specific information listed in the regulation, as long as the pedigree otherwise identifies the last authorized distributor of record that handled the drugs and the associated dates of the transactions, as well as the names and addresses of all unauthorized distributors that handled the drug after the last authorized distributor, and the corresponding dates of those transactions.

In summary, unauthorized distributors need to be aware that their pedigree(s) must: (1) Include information regarding transactions going back to either the manufacturer or the last authorized distributor of record that handled the drugs, consistent with the preliminary injunction order previously referenced and (2) include the date of the transaction and the names and addresses of all parties to the transaction as explicitly required under section 503(e)(1)(A) of the FD&C Act. Furthermore, while FDA is proposing to remove § 203.50(a) and intends to exercise enforcement discretion under these described circumstances with respect to the statutory requirements for a pedigree, FDA encourages wholesalers to include the drug, dosage, container size, number of containers, and the drug's lot or control number(s) in the pedigree as well.

FDA continues to believe that drug supply chain security is of the utmost importance and that transparency of transactions and accountability are essential to further secure our nation's drug supply. Counterfeit and diverted drugs continue to be found in our drug supply chain and the action proposed in this document should not be interpreted to mean that there is not a problem with counterfeit and diverted drugs. Rather, FDA remains committed to the framework set forth in the 2004 FDA Counterfeit Drug Task Force Report (Task Force Report) and subsequent updates to that Task Force Report (*http://www.fda.gov/Drugs/DrugSafety/ucm169825.htm*) and will continue to move forward, working with the private and public sectors to improve the security of the drug supply chain and implement measures to further protect Americans from counterfeit and diverted drugs. We also will continue our efforts to implement the pharmaceutical security provisions contained in section 913 of the Food and Drug Administration Amendments Act of 2007.

As stated in the Task Force Report, such measures include implementation of tracking and tracing, which would help secure the integrity of the supply chain by providing an accurate electronic record of transactions in the drug supply chain. Such electronic records documenting the movement of a drug product from the manufacturer to the dispenser would be an important step in preventing counterfeit and diverted drugs from entering the drug supply chain. FDA will continue to develop standards for the purpose of securing the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs, including standards for the identification, validation, authentication, and tracking and tracing of prescription drugs. We are not proposing any new provisions in lieu of § 203.50(a) at this time.

III. Legal Authority

FDA is issuing this proposed rule to remove the provisions in § 203.50(a) under its rulemaking authority under section 701(a) of the FD&C Act (21 U.S.C. 371) and based on those reasons provided in section II of this document. Specifically, FDA can issue regulations through its rulemaking authority to establish requirements for section 503(e) of the FD&C Act. As described in section I of this document, FDA previously issued a final rule establishing certain requirements for section 503(e)(1)(a). Similarly, under its rulemaking authority, FDA can propose to remove those specific requirements that have been established by regulation. FDA is basing the proposed removal of § 203.50(a) on the grounds described in section II of this document. As explained earlier, the statutory provisions of section 503(e) of the FD&C Act, as well as the other provisions of § 203.50 that would not be removed by this proposed rule, would remain legally effective.

IV. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the removal of the specified pedigree requirements for prescription drug distribution in § 203.50(a) would not measurably decrease the estimated compliance costs of the December 1999 final rule, the Agency proposes to certify that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

The Agency published a final rule on December 3, 1999, codified in § 203.50(a), that contained certain requirements concerning prescription drug distribution. Specifically, it required that before the wholesale distribution of any prescription drug to another wholesale distributor or retail pharmacy for which the seller is not an authorized distributor of record, the wholesale distributor must provide to the purchaser a statement identifying each prior sale, purchase or trade. Further, it contained a list of specific information to be contained in the identifying statement. As explained previously, this regulation is the subject of a preliminary injunction. In the December 1999 final rule, the Agency estimated that the wholesale distribution requirements, including the drug identifying (or origin) statement and a separate distributor list to be provided by manufacturers, would together impose $258,000 in annual recordkeeping costs. In making this estimate, the Agency judged that the marginal costs for the inclusion of the additional information that § 203.50(a) would have required beyond that information that would be required in the PDMA pedigree provision would be negligible, and did not increase its cost estimate to reflect this additional effort. The removal of § 203.50(a), therefore, is expected to reduce compliance costs by only that negligible amount that the Agency did not separately estimate for the final rule, as the pedigree provision of the PDMA still requires its own, slightly less expansive, pedigree provision. This regulatory action that removes a provision of the December 1999 final rule is expected to reduce the previously estimated annual compliance costs of $258,000 for this provision by a negligible, but unquantified, amount.

V. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. Environmental Impact

The Agency has determined under 21 CFR 25.30 this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. Proposed Effective Date

The Agency is proposing that any final rule that may issue based upon this proposed rule become effective upon its publication in the **Federal Register**.

IX. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 203

Labeling, Prescription drugs, Reporting and recordkeeping requirements, Warehouses.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 203 be amended as follows:

PART 203—PRESCRIPTION DRUG MARKETING

1. The authority citation for 21 CFR part 203 continues to read as follows:

Authority: 21 U.S.C. 331, 333, 351, 352, 353, 360, 371, 374, 381.

§ 203.50 [Amended]

2. Section 203.50 is amended by removing and reserving paragraph (a).

Dated: July 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–17696 Filed 7–13–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF STATE

22 CFR Part 123

RIN 1400–AC85

[Public Notice 7524]

International Traffic in Arms Regulations: International Import Certificate

AGENCY: Department of State.

ACTION: Proposed rule.

SUMMARY: The Department of State proposes to amend the International Traffic in Arms Regulations (ITAR) to remove reference to the International Import Certificate. This amendment will effectively cease the Department's current practice of accepting DSP–53 submissions, as there is no statutory, regulatory, or other authoritative basis for the Department to do so.

DATES: The Department of State will accept comments on this proposed rule until August 29, 2011.

ADDRESSES:

Interested parties may submit comments within 45 days of the date of the publication by any of the following methods:

- *E-mail: DDTCResponseTeam@state.gov* with the subject line, ''International Import Certificate, ITAR Section 123.4.''
- *Internet:* View this notice by searching for its RIN number on the U.S. Government regulations Web site at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Samuel C. Harmon, Office of Defense Trade Controls Policy, Department of State, by *telephone:* (202) 663–2728; *fax:* (202) 261–8199; or *e-mail: harmonsc@state.gov.* ATTN: International Import Certificate, ITAR Section 123.4.

SUPPLEMENTARY INFORMATION: The Arms Export Control Act authorizes the President to control the import and export of defense articles. Executive Order 11958, as amended, delegated the authority to regulate permanent exports and temporary imports and exports of defense articles to the Department of State, and delegated the authority to regulate permanent imports to the Attorney General. The International Import Certificate (IIC), Form BIS–645P/ATF–4522/DPS–53, is identified as a form issued by the Department of Commerce's Bureau of Industry & Security; the Department of Justice's Bureau of Alcohol, Tobacco, Firearms and Explosives; and the Department of State's Directorate of Defense Trade Controls (DDTC). It is meant to